

## **A Closer Look at Biobanking of Newborn Blood Spots**

Posted by [Bob Bryan](#) on July 1, 2009

Under [established state public health programs](#), hospitals nationwide collect blood samples from the majority of the more than 4 million U.S. newborns each year to screen for genetic and metabolic disorders. This is widely viewed as a valuable program that can lead to early diagnosis and treatment of potentially serious conditions and is normally controversial only when the parents object to testing.

At present, although there is [some national coordination of newborn screening programs](#), there is no uniform policy governing the disposition of newborn blood samples after screening is complete. Some states store the samples for a limited period of time and then discard them. Others, including Minnesota and Michigan, permit researchers to use the samples, including to conduct pilot studies designed to develop additional newborn screening tests. Michigan is even facilitating (although not funding) the development of a "[Neonatal BioTrust](#)" in the hopes of drawing biomedical companies to the state.

And additional guidance from the federal government is likely forthcoming. Late last year the National Institute of Child Health and Human Development, a division of the [National Institutes of Health](#) (NIH), awarded the [American College of Medical Genetics](#) (ACMG) a [\\$13.5 million, 5-year contract](#) for the development of a National Newborn Screening Translational Research Network. One of the network's many aims is to facilitate the creation of a "reliable repository of residual dried bloodspots that is either virtual or physical and comprised of those stored by state newborn screening programs and other resources."

As pointed out in [an article in today's Washington Post](#), the increasing focus on what happens to newborn blood spots after screening has led some parents and advocacy groups to question the existing practices. In Minnesota, an advocacy group has questioned that state's practice of retaining newborn blood spots for research use, [arguing that parental consent for ongoing storage and use, including research, should be required](#). [Litigation is ongoing in both Minnesota and in Texas](#). In response, the ACMG recently published a position statement on the [Importance of Residual Newborn Screening Dried Blood Spots](#).

The newborn blood spot debate covers ground that is all too familiar in the context of more traditional genetic testing, including whether and when informed consent should be required prior to reusing samples or data for research and to what degree individuals (or in this case the parents of newborns) should have control over the types of studies for which such samples are used.

Under the [2008 Newborn Screening Saves Lives Act](#), the [Advisory Committee on Heritable Disorders in Newborns and Children](#), which reports to the Secretary of [Health and Human Services](#), has been tasked with a review of the issues surrounding current and proposed newborn screening programs and practices. As these issues continue to draw considerable public attention, the committee's analysis — which may be presented as soon as its next meeting in September — is a development to keep an eye on.

For more:

- [Overview of the CDC's role in newborn screening](#), including information on the Newborn Screening Quality Assurance Program (NSQAP) and the Newborn Screening National Contingency Plan.
- A list of [Newborn Genetic and Metabolic Disease Screening statutes](#) prepared by the [National Conference of State Legislatures](#).